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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,074	04/21/2004	Robert Falotico	CRD0931CIP	5950

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WOODCOCK WASHBURN LLP
CIRA CENTRE, 12TH FLOOR
2929 ARCH STREET
PHILADELPHIA, PA 19104-2891

EXAMINER	
KENNEDY, SHARON E	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/829,074	FALOTICO ET AL.	
	Examiner	Art Unit	
	Sharon E. Kennedy	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-5, 7, 8, 13, 14, 16, 18, 19 of copending Application No. 10/431,059 with reference to view of Boston Scientific, "Measuring DES Efficacy," www.taxus-stent.com/usa/efficacy.html, pages 1-3, copyright 2006, hereinafter "Boston Scientific-2006". The claims of the '059 application recite a method of preventing lesion restenosis by using an implantable medical device having the compound rapamycin and the medical device. Applicant's claims are directed to a method of inhibiting neointimal proliferation resulting from transluminal coronary angioplasty comprising, e.g., using a stent having FKBP12,

rapamycin, etc, and the device. Applicant's claims further recite a specific in-stent late loss. Boston Scientific explains that this terminology indicates, roughly at best, the efficacy of the drug in the medical device. Accordingly, in view that the in stent late loss limitation is not accorded much patentable weight since it is not an accurate measure of efficacy, and in view that the prior applied for claim already recites the rapamycin antiproliferative, the claims are provisionally rejected.

Applicant should take note that in this rejection, and in the following rejections, the Boston Scientific reference has a publication date of probably 2006, after the filing date of this application. However, this reference is being used to discuss the inherent scientific aspects of claiming an in stent late loss, and is not being used as prior art. It is being used as evidence to show that a characteristic not disclosed in the reference in inherent.

This is a provisional obviousness-type double patenting rejection.

Claims 15-22, 31-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 10 of copending Application No. 10/742,346 with reference to view of Boston Scientific-2006. The '346 application claim 10 recites an implantable medical device comprising the antiproliferative rapamycin. Applicant's claims are directed to a stent comprising, e.g., rapamycin and recite a specific in-stent late loss. Boston Scientific explains that this terminology indicates, roughly at best, the efficacy of the drug in the medical device. Accordingly, in view that the in stent late loss limitation is not accorded much patentable weight since it is not an accurate measure of efficacy, and in view that the prior applied

for claim already recites the rapamycin antiproliferative, the claims are provisionally rejected.

This is a provisional obviousness-type double patenting rejection.

Claims 15-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 10/761,032 with reference to view of Boston Scientific-2006. The claims of the '032 application recite an implantable medical device and method comprising the rapamycin. Applicant's claims are directed to a stent comprising, e.g., rapamycin and recite a specific in-stent late loss. Boston Scientific explains that this terminology indicates, roughly at best, the efficacy of the drug in the medical device. Accordingly, in view that the in stent late loss limitation is not accorded much patentable weight since it is not an accurate measure of efficacy, and in view that the prior applied for claims already recite the rapamycin antiproliferative, the claims are provisionally rejected.

This is a provisional obviousness-type double patenting rejection.

Claims 15-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/796,397 with reference to view of Boston Scientific-2006. The claims of the '397 application recite an implantable medical device and method of use comprising rapamycin. Applicant's claims are directed to a stent and method of use comprising, e.g., rapamycin and recite a specific in-stent late loss. Boston Scientific explains that this terminology indicates, roughly at best, the efficacy of the drug in the medical device. Accordingly, in view that the in stent late loss limitation is not accorded

much patentable weight since it is not an accurate measure of efficacy, and in view that the prior applied for claim already recites rapamycin, the claims are provisionally rejected.

This is a provisional obviousness-type double patenting rejection.

Claims 15-36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,776,796 in view of Boston Scientific-2006. The claims of the '796 patent are directed to a stent and method including the therapeutic agent rapamycin. Applicant's claims 13-22 are directed to a stent comprising, e.g., rapamycin and recite a specific in-stent late loss. Boston Scientific explains that this terminology indicates, roughly at best, the efficacy of the drug in the medical device. Accordingly, in view that the in stent late loss limitation is not accorded much patentable weight since it is not an accurate measure of efficacy, and in view that the prior patent claims already recite rapamycin, the claims are rejected.

Claims 15-22, 31-36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,808,536 in view of Boston Scientific-2006. The claims of the '536 patent are directed to a stent including the therapeutic agent rapamycin. Applicant's claims 13-22 are directed to a stent comprising, e.g., rapamycin and recite a specific in-stent late loss. Boston Scientific explains that this terminology indicates, roughly at best, the efficacy of the drug in the medical device. Accordingly, in view that the in stent late loss limitation is not accorded much patentable weight since it is not an accurate measure of efficacy,

and in view that the prior patent claims already recite rapamycin, the claims are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims require a specific in-stent late loss efficacy, as claimed in the independent claims. Boston Scientific-2006, is cited to show the inherent indefiniteness of this limitation. In-stent late loss, as shown in the article, does not provide any useful information as to the efficacy of a stent delivery device. See especially the second diagram in the reference, describing "CASE A" and "CASE B". As shown, in-stent late loss has little meaning when describing the functionality of a device as compared to in-segment late loss. Applicant may argue that this is irrelevant, since the in-stent loss can be measured and quantified regardless of its usefulness as a data point. However, the examiner takes the position that this characteristic places a potential infringer in an untenable position since the data holds no real value. Although applicant claims a specific numerical range, less than about 0.5 mm, the metes and bounds of this range are indefinite because the standard for measuring the data is unclear. See MPEP 2173.05(c), reproduced below for applicant's convenience.

2173.05(c) Numerical Ranges and Amounts Limitations

Generally, the recitation of specific numerical ranges in a claim does not raise an issue of whether a claim is definite.

I. **NARROW AND BROADER RANGES IN THE SAME CLAIM**

Use of a narrow numerical range that falls within a broader range in the same claim may render the claim indefinite when the boundaries of the claim are not discernible. Description of examples and preferences is properly set forth in the specification rather than in a single claim. A narrower range or preferred embodiment may also be set forth in another independent claim or in a dependent claim. If stated in a single claim, examples and preferences lead to confusion over the intended scope of the claim. In those instances where it is not clear whether the claimed narrower range is a limitation, a rejection under 35 U.S.C. 112, second paragraph should be made. The Examiner should analyze whether the metes and bounds of the claim are clearly set forth. Examples of claim language which have been held to be indefinite are (A) "a temperature of between 45 and 78 degrees Celsius, preferably between 50 and 60 degrees Celsius"; and (B) "a predetermined quantity, for example, the maximum capacity."
While a single claim that includes both a broad and a narrower range may be indefinite, it is not improper under 35 U.S.C. 112, second paragraph, to present a dependent claim that sets forth a narrower range for an element than the range set forth in the claim from which it depends. For example, if claim 1 reads "A circuit ... wherein the resistance is 70-150 ohms." and claim 2 reads "The circuit of claim 1 wherein the resistance is 70-100 ohms.", then claim 2 should not be rejected as indefinite.

The claims are also indefinite in view of the language "rapamycin or a macrocyclic triene analog thereof". Applicant published specification paragraph [0040] states that "rapamycin used in this context includes rapamycin and all analogs, derivatives and congeners." There is also a broadening phrase set in the last line of applicant's published paragraph [0047]. It is unclear how these phrases affect the scope of the claims, accordingly, the claims are indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 15-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell et al., US 5,288,711 in view of Kamath et al., US 6,335,029..

This application is a continuation in part of applicant's prior application, US Serial No. 09/575,480. The claims of that application are under appeal. The file history of that application is incorporated herein.

The claims of the present application differ from the '480 application by reciting an in-stent late loss and requiring that the drug be rapamycin or a macrocyclic triene analog thereof. Taxol (Paclitaxel) is not a macrocyclic triene.

Kamath, applied in the parent application, discloses the claimed invention except Kamath applies taxol instead of rapamycin as the drug delivered. In the '480 application, the examiner relied on applicant's disclosure on page 8, lines 25-27, which places taxol, vincristine and rapamycin in a Markush type grouping, which is an admission that the compounds have equivalent functionalities in stents. The present specification does not include this Markush grouping.

The examiner does not find this to be convincing evidence that applicant does not consider these drugs to be equivalents for the proposed use. The primary reference, Mitchell '711, has a publication date of 1994, and is cited to exemplify that the use of rapamycin in stents to prevent smooth muscle cell hyperplasia after balloon angioplasty has been well known for some time. However, Mitchell does not explicitly disclose the polymeric coatings claimed, merely stating (column 4, lines 5-7) that a "vascular stent can be impregnated with ... rapamycin." The secondary reference, Kamath, exemplifies that incorporating antiproliferative drugs in polymeric coatings on stents is rudimentary. Accordingly, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have use rapamycin in any stent having a polymeric coating, such as the Kamath stent, so that the rapamycin would be delivered to the intraluminal area of interest.

Regarding applicant's limitation directed to in-stent late loss, this numerical characteristic only vaguely, at best, defines the effectiveness of the stent. In view of the deficiencies in the definiteness of this embodiment (as explained in previous rejections), the in-stent late loss is considered to be within the scope of the ordinary artisan. In-

stent late loss findings are dependent upon the amount of drug incorporated into the stent, the release rate of the drug, the polymeric binding of the drug, the degree to which the blood vessel was initially blocked or partially blocked, the degree to which the artery was widened by the angioplasty, the health and age of the patient, and numerous other factors. All of these parameters are within the skill of the surgeon to control. Accordingly, the specifically claimed in-stent late loss is obvious to one of ordinary skill in the art.

Applicant has submitted new claims 31-36 directed to the drug dosage of rapamycin/analog. The examiner takes the position that this is merely a recitation of a "prescription-type" claim and does not set forth anything unusual or unexpected. Citing a particular range or dosage is merely akin to providing a dosage amount of any drug for a patient in the absence of a showing of criticality. It is simply up to the surgeon or doctor to determine what dosage a patient needs and how long the drug should be administered. If a patient is in need of pain medication, it is a simple matter to decide how much medicine should be provided and how long the patient should take the medicine. Every person who has ever suffered a migraine headache readily understands this concept. Similarly, it is well known that drug eluting stents are designed according to patient need. These are concepts which are merely observed and learned by a surgeon during the ordinary course of patient examination.

Specifically with regard to Mitchell '711, this concept is explained therein. As set forth in column 7, lines 26+, Mitchell states, "The dosage requirements vary with the particular compositions employed, the route of administration, the severity of the

symptoms presented and the particular subject being treated." There is nothing unusual about discovering a particular drug dosage in the absence of a showing of criticality.

Response to Arguments

Applicant's arguments filed January 18, 2007 have been fully considered but they are not persuasive. Regarding the rejection under 35 U.S.C. 112, applicant presents several articles comparing the reliability of observations between in-stent late loss and in-segment late loss in predicting target lesion revascularization (TLR). The examiner's relied on reference and applicant's submitted references discuss different types of drug eluting stents. At a minimum, these references collectively show that these types of measurements are not universal, they must be carefully analyzed for each type of drug eluting stent, and are not a predictor of stent efficacy across the board. Accordingly, the examiner takes the position that these articles collectively affirm the examiner's rejection under 35 U.S.C. 112 in view that the outcome for predicting the TLR using in-stent LL or in-segment LL differed.

Further, the examiner takes the position that the Mauri '321 does not purport to prove the efficacy measuring in-stent versus in-segment LL. The thrust of the article is set forth in the "Conclusion" section of the Abstract. The point is to promote the use of transformation to improve the accuracy of predicting low binary restenosis rates. This has nothing to do with advocating one measuring data-collection technique over the other, but is relevant to the manner in which the data are "crunched" (log, square root, log normal, log-logistic, power), which is a statistical examination performed to provide

useful information. A careful reading of the article will show that while in-stent LL was more effective in one single aspect, that pointed out by applicant, it was not statistically relevant in other stents.

Applicant has submitted new claims 31-36 which sets forth an amount of rapamycin/analog. These limitations, in combination with the description of late loss, yield useful information sufficient to place a potential infringer on notice. Accordingly, these claims are not rejected under 35 U.S.C. 112.

Conclusion

Applicant did not address the obvious double patenting rejections in the previous response of January 8, 2007. Applicant must either argue the rejections or file the appropriate terminal disclaimers in response to this office action.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The patent to Kaplan, US 5,342,348, contains a statement similar to the Kamath patent, stating in column 2, lines 15-20 that it is well known for a drug delivery device to operate for weeks or months.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharon E Kennedy

Sharon E. Kennedy
Primary Examiner
Art Unit 1615